

TRANSMITTAL AND NOTICE OF APPROVAL OF  
STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER:

04 -- 009

2. STATE:

MAINE

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL  
SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR  
CENTERS FOR MEDICARE AND MEDICAID SERVICES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE(S)  
MAY 3, 2004

5. TYPE OF PLAN MATERIAL (CHECK ONE):

☐ NEW STATE PLAN

☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN

☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate Transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION:

7. FEDERAL BUDGET IMPACT:

a. FFY 04 \$ 0

b. FFY 05 \$ 0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:  
ATTACHMENT 3.1-E ENTIRE SECTION

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION  
OR ATTACHMENT (If Applicable):  
ATTACHMENT 3.1E ENTIRE SECTION

SUBJECT OF AMENDMENT: UPDATE TRANSPLANT CRITERIA. AND PRIOR AUTHORIZATION REQUIREMENTS

11. GOVERNOR'S REVIEW (Check One):

- ☐ GOVERNOR'S OFFICE REPORTED NO COMMENT  
☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED  
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

☒ OTHER, AS SPECIFIED  
COMMISSIONER, DEPT. OF HUMAN SERVICES

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:

JOHN R. NICHOLAS

14. TITLE:

Commissioner, Maine Department of Human Services

15. DATE SUBMITTED: JUNE 30, 2004

16. RETURN TO:

CHRISTINE ZUKAS-LESSARD  
Acting Director, Bureau of Medical Services  
#11 State House Station  
442 CIVIC CENTER DRIVE  
Augusta, ME 04333-0011

17. DATE RECEIVED:

21. TYPED NAME:

23. REMARKS:

Approved: 08/26/04  
effective: 05/03/04

State/Territory: Maine

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STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

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COVERED ORGAN TRANSPLANT PROCEDURES

MaineCare reimburses for services related to organ transplants only when all criteria of this section are met, and a Department-approved transplant center recommends that the transplant be performed. MaineCare does not cover transplants that are considered experimental or investigational in nature.

MaineCare covers procedures (evaluations and transplants) that include, but are not limited to: heart, heart-lung, bone marrow (autologous and allogeneic bone marrow or stem cell transplants), kidney, corneal, liver, lung, small intestine, combined liver-small intestine, and pancreas transplants.

NON-COVERED TRANSPLANT SERVICES

MaineCare will not cover evaluations for transplant or transplants if any of the following apply:

- a. Another procedure of lower cost and of less risk may achieve the same or similar result; or
- b. The transplant is not expected to make a significant difference in the member's health and/or performing the transplant will serve primarily an academic purpose; or
- c. The transplant is contraindicated by the medical condition, age, and prognosis of the member; or
- d. The transplant center and/or the member's specialist do not recommend that the evaluation for transplant or transplant be performed.

TRANSPLANTS NOT REQUIRING PRIOR AUTHORIZATION

a. In-State Transplant Procedures Not Requiring Prior Authorization

The following transplant procedures and evaluations do not require prior authorization, as long as they are performed in the State of Maine:

- 1) Kidney Transplants. Title XVIII of the Social Security Act of the Medicare program reimburses for kidney transplants for members with end stage renal disease. For members who are dually eligible for both Medicare and MaineCare, MaineCare will reimburse for only Medicare coinsurance and deductible costs customarily reimbursed by MaineCare.
- 2) Corneal Transplants. MaineCare covers corneal transplantation to correct corneal opacity or keratoconus.

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- 3) Autologous or Allogeneic Bone Marrow or Stem Cell Transplants. MaineCare covers bone marrow or stem cell transplants. MaineCare covers these procedures when used to replace bone marrow damaged by high doses of radiation therapy or chemotherapy.

TRANSPLANTS REQUIRING PRIOR AUTHORIZATION

All transplants and transplant evaluations performed outside the State of Maine require prior authorization, as described in MBM, Chapter I. All transplants and transplant evaluations require prior authorization unless the transplant meets the criteria of 90A-03 above:

a. Transplant Procedures Requiring Prior Authorization

MaineCare will consider prior authorization for organ transplants when all of the following criteria are met:

- 1) Both the transplant center and the member's in-state specialist recommend that the transplant be authorized after the member is evaluated; and
- 2) The transplant meets all other criteria specified in Section 90 and this Appendix; and
- 3) MaineCare has received complete documentation from the transplant center to make a determination.

b. Overview of the Authorization Process

The provider must submit complete documentation and all criteria listed in this section must be met before MaineCare will consider requests for prior authorizations for evaluations and transplant services. In making a determination, MaineCare will utilize appropriate staff including but not limited to Bureau of Medical Services medical consultants, a medical specialist in the relevant field of the requested transplant (e.g. cardiologist for heart transplants), a psychiatrist or psychologist and designee(s) of the Director of the Bureau of Medical Services. MaineCare prior authorization staff will review the materials and make a determination by considering established patient selection and facility criteria within this section. To make its decision, the Department will also look for evidence that the request conforms to general and organ specific patient selection criteria, and recommendations of relevant medical specialists.

The Department will notify the requesting physician, other appropriate providers, and the member of the decision whether an evaluation or transplant is prior authorized within 30 days of the request. Members may appeal decisions based on information in the MaineCare Benefits Manual, Chapter I, General Administrative Policies and Procedures.

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c. Documentation for Prior Authorization

The Department will make a decision regarding prior authorization for the transplant procedure after reviewing the transplant center's report submitted to the MaineCare Prior Authorization Unit. The report must include written assessments performed by the appropriate specialists and recommendations regarding all possible treatment options. The report must also include the specialists' general assessment of the member's anticipated prognosis and the risks and benefits (e.g. quality of life) associated with each potential treatment option, including transplant.

Providers must clearly document all of the following information concerning the member's health in the written report:

- 1) Diagnosis;
- 2) Pertinent medical history;
- 3) Alternate treatments performed and their results;
- 4) Recommended transplant procedure;
- 5) Expected prognosis after recommended treatment;
- 6) Second opinion of the member's condition from a board-certified specialist affiliated with a tertiary care hospital. This assessment must be based upon a review of the member's medical records and previous diagnostic studies and must provide recommendations regarding all possible treatment options for the member. Based upon the consultant's experience with similar cases, the report must also include the consultant's general assessment of the member's prognosis and of the risks and benefits (i.e., quality of life) associated with each potential treatment option, including transplant; and
- 7) A report of an assessment by a mental health professional for members age 19 and older who are being assessed for transplants other than a bone marrow transplant. The assessment must address the member's mental health and ability to understand both the procedure and its psychological aftermath. This report shall include comments on the member's ability to take medications and comply with medical recommendations and on the member's family or other support system's ability to assist the member in coping with both the procedure and its psychological aftermath. The professional must state that the member is currently (in the prior four weeks) not abusing drugs or alcohol and has agreed to any on-going counseling recommended regarding drug or alcohol abuse.

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- 8) A written medical record release signed by the member or the member's guardian.

MaineCare prior authorization staff may require additional information to make a determination.

Providers must submit the request for prior authorization for transplant evaluations and transplant services to:

MaineCare Prior Authorization Unit  
Bureau of Medical Services  
Department of Human Services  
11 State House Station  
Augusta, Maine 04333-0011

d. Duration of Prior Authorization

Any prior authorization for reimbursement for an organ transplant procedure shall expire one year after the date of prior authorization. If the transplant procedure has not been performed within that period, then prior authorization must once again be sought for the member.

Providers must repeat the prior authorization process for re-authorization. This second review will focus on reassessing the member's condition and updating the information submitted for the initial authorization. MaineCare will utilize this information to make the appropriate final decision regarding re-authorization for an evaluation and approval or denial of coverage for the transplant.

e. Patient Selection Criteria

1) General Selection Criteria:

Members must meet all of the following general criteria before MaineCare grants prior authorization of the evaluation and/or the transplant:

- a. The member's overall physiological condition must indicate a reasonable expectation for success; and
- b. Alternative medical therapies have been tried and have failed or, if tried, would not prevent progressive disability or death; and
- c. There is every reasonable expectation that the member will strictly adhere to the difficult long-term medical regimen required; and

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- d. The member is emotionally stable and has a realistic attitude toward illness; and
- e. Current history (current and for at least four weeks preceding the transplant evaluation and actual transplant) is free of alcohol or drug abuse; and
- f. There is a reasonable likelihood that the transplant will extend the member's life expectancy at least two years and to restore a range of physical and social functions of daily living; and
- g. The member meets all established criteria and presents no contraindications set by the approved transplant center for the specific transplant procedure; and
- h. The member has been evaluated by a transplant facility approved by the Department and the transplant center has recommended the transplant and indicated a willingness to perform the procedure.

2) Specific Selection Criteria:

In addition to the general selection criteria stated above, each member must meet all transplant center specific criteria for each transplant. These criteria are set by the transplant center and include indications and contraindications for specific organ transplant procedures based on national standards. The Department will not prior authorize any transplant if the transplant center does not approve the procedure based on all specific selection criteria set by the transplant center.

CRITERIA FOR SELECTION OF TRANSPLANT CENTERS

MaineCare will only cover transplants performed in Department-approved transplant centers.

While physicians may request specific transplant centers, the Department reserves the right to select the transplant center a specific transplant is approved for. Whenever possible, the Department will approve the physician's request for the site of the member's organ transplant evaluation. If several Department-approved transplant centers are available for specific transplants, the Department reserves the right to authorize the transplant in the most cost-effective transplant center. When all other factors are equal, the Department will give preference to the provision of services at an in-state or regional transplant center in order to enhance continuity of care by minimizing the distance that the member and family will have to travel for evaluation, the transplant procedure, and after-care.

- a. Initial Approval of Out-of-State Transplant Centers (Not required for existing kidney transplant facilities or for any corneal or bone marrow transplant facility):

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To approve the use of an out-of-state transplant center facilities must have the following:

- 1) Initial approval of an out-of-state transplant center requires documentation of a survival rate for the relevant transplant procedure comparable with the national experience. This survival rate must be based on a sufficient number of procedures (e.g. 12 procedures over the past 12 months) to enable the Department to compare the new transplant center with other national transplant centers that are performing the procedure.

b. On-going Approval of Out-of-State Transplant Centers:

The Department will approve out-of state transplant center facilities on a continuing basis using the following criteria:

- 1) The transplant center has personnel experienced with the relevant specialized surgeries, infectious diseases, pediatrics, pathology, pharmacology, anesthesiology, tissue typing, immunological and immunosuppressive techniques and blood bank support services; and
- 2) The center has a consistent, equitable, and practical protocol for selection of candidates and, at a minimum, must adhere to the Department's General Patient Selection Criteria; and
- 3) The center has adequate services to provide emotional and social support for members and their families; and
- 4) The center has satisfactory arrangements for donor procurement services; and
- 5) The center has demonstrated willingness and the ability to provide relevant information to the member's physicians, to MaineCare staff, and to other transplantation center personnel; and
- 6) The transplant center maintains all required federal, state, or provincial accreditations and certifications; and
- 7) The transplant center is a Medicare approved transplant center for all applicable transplants, including heart, lung, heart-lung, liver, and intestinal transplant centers; and
- 8) The transplant center maintains conformance to the national survival rate criteria as described in (a) above; and

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9. The transplant center must maintain continuing approval dependent upon meeting all above criteria. The transplant center must report any changes in status regarding meeting the above criteria to the Department.

c. Initial Approval for In-State Transplant Centers

The Department will waive conformance to the national survival rate criteria described in (a) above for any new in-state transplant centers for a two-year period. All other criteria described above must be met. This two-year start-up period, which will begin with the first transplant procedure performed in the in-state facility, is designed to enable the in-state transplant center to secure sufficient experience to obtain a survival rate that can be compared with national experience.

d. Continued Approval for In-State Transplant Centers

Continued approval for the in-State center after this two-year start-up period requires evidence of a survival rate that is comparable with the national experience and of success with and safety of the transplant procedure. The Department must be able to base this survival rate on a sufficient number of procedures to enable the Department to compare the in-state transplant center with other national transplant centers that are performing the procedure. The in-state transplant center must meet all other criteria described in (b) above in order to receive continued transplant center approval. The transplant center must report any changes in status regarding meeting the above criteria to the Department.

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